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EXAMINER

KASZTEJNA, MATTHEW JOHN

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/760,520
Filing Date: January 21, 2004
Appellant(s): FREED, DAVID I.

Philip J. Hoffmann
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 7, 2008 appealing from the Office action mailed September 5, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,682,599	Konomura	7-1987
6,660,011	Levinson	12-2003
5,599,324	McAlister et al.	2-1997
5,871,440	Okada	2-1999
4,204,528	Termanini	5-1980

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4, 10-18, 28-30, 31-37, 39-40, 43-44, 45-46, 47-52, 53, 56, 58-64, 66-67 and 97-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson.

In regards to claims 1, 28, 34, 47-52, 58-63 and 97-100, Konomura discloses a medical device comprising: a proximal handle; an elongated member 2 having a proximal end, a distal end, and a lumen there between, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body; an end effector 6 proximate the distal end of the elongated member, actuation of the proximal handle 14 causing the end effector to perform a medical procedure; and a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member (see Figs. 1 and 2, and Col. 4, Lines 1-14). Konomura is silent with

respect to a tissue cutting end effector wherein actuation of the proximal handle causes the end effector to sever tissue. Konomura teaches of wires 6 used for holding or fracturing a foreign matter. Levinson teaches of an analogous medical device used for tissue cutting and retrieval, having a tissue cutting end effector that is a snare loop 28 (see Fig. 5). The device consists of a set of wires 28 used for selectively cutting tissue within the body, as the wires 28 may be energized so that the wires cut tissue captured within the wires 28 (see Figs. 1 and 9). It would have been obvious to one skilled in the art at the time the invention was made to have a tissue cutting end effector in the apparatus of Konomura to selectively capture, cut and/or retrieve polyps and other aggregates of organic tissue from a patient's internal organs as taught by Levinson.

In regards to claims 2, 35 and 66, Konomura discloses a medical device wherein the flow path defined by the distal member has a cross-sectional flow area less than a cross-sectional flow area of the lumen (see Fig. 2)

In regards to claims 3-4 and 36, Konomura discloses a medical device including a port 10 which is in fluid communication with the lumen and comprises a fluid supplying member for supplying fluid to the port (see Col 3, Lines 20-25).

In regards to claims 10-13 and 37, Konomura discloses a medical device wherein the distal member includes a sealing member 7. At least a portion of the distal member has a frusto-conical shape for substantially closing the lumen. The distal member includes a base portion and a head portion, the base portion having an outer diameter substantially the same as an inner diameter of the lumen, the head portion having an outer diameter greater than the inner diameter of the lumen. Also, the distal

member includes a plate member having an outer diameter substantially the same as the inner diameter of the lumen (see Col. 3, Line 64 – Col. 4, Line 13).

In regards to claims 14-15, Konomura discloses a medical device wherein at least a portion of the flow path has a cross-sectional flow area smaller than that of at least one of an inlet and an outlet of the flow path (see Col. 4, Lines 36-68).

In regards to claims 16-18, 39-40, 43-44, 56 and 67, Konomura discloses a medical device wherein the distal member connects to the end effector at a distal end of the end effector and the distal member is movable relative to the lumen and is configured to substantially close the lumen when the end effector retracts (see Fig. 1 and Col. 4, Lines 1-14).

In regards to claims 28-30, Konomura discloses a medical device wherein the handle includes a stationary part 15 and movable part 14. Further comprising a control member 5 having a proximal end coupled to the movable part and a distal end coupled to the end effector so that actuation of the movable part relative to the stationary part enables movement of the end effector for performing the medical procedure (see Fig. 1 and Col. 3, Lines 26-47).

In regards to claims 31-32, 45, 53 and 64 Konomura discloses a medical device but is silent with respect to an electrical connector for receiving cautery current from a power supply source. Levinson teaches of an electrical connector for attachment to a cauterizing endoscopic snare (see Col. 5, Lines 15-20). It would have been obvious to one skilled in the art at the time the invention was made to include such an electrical connector in on the device of Konomura in order to provide the snare loop with

an electrical current and therefore assist in surgical procedures, as taught by Levinson and is well-known in the art.

In regards to claim 33 and 46, Konomura discloses a medical device wherein the distal member defines a plurality of flow paths (see Fig. 5).

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson in further view of U.S. Patent No. 5,599,324 to McAlister et al.

In regards to claims 5-7, Konomura and Levinson disclose a medical device but are silent with respect to a fluid supply member (syringe) for supplying fluid to the port, an interlocking member and fluid chamber sealed from a portion of the handle. McAlister et al. teach of an analogous device in which a physician can attach a syringe or other device to the second entry port 31 and force a contrast agent through the passage 35, the central volume 33 and the lumens 23 and 24 in parallel to be discharged where the lumens 23 and 24 exit the distal end 17. The seals formed between the tube 36 and the handle 12 and between the tube 36 and the catheter tube 11 around the guidewire 22 assure isolation of the guidewire lumen 22 (see Col. 5, Lines 13-22). It would have been obvious to one skilled in the art at the time of the invention to include a fluid supply assembly in the device of Konomura and Levinson so if it is necessary to relocate the distal tip 20, there is no need to remove the guidewire as taught by McAlister et al.

Claims 69-75, 81-82, 89, 93 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson in further view of U.S. Patent No. 5,871,440 to Okada.

In regards to claims 69, 89 and 93, Konomura and Levinson discloses a medical device comprising: a proximal handle; an elongated member 2 having a proximal end, a distal end, and a lumen there between, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body; a tissue cutting end effector proximate the distal end of the elongated member, actuation of the proximal handle 14 causing the end effector to sever tissue; and a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member. Konomura and Levinson are silent with respect to wherein at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path. Konomura teach that the number of openings is not limited and that a plurality of openings may be formed through which fluid may be passed (see Col. 4, Lines 36-65). Okada teaches of an analogous surgical instrument having a nozzle 374 for dispensing fluid. Okada teaches of a nozzle capable of having a large variety of configurations and cross-sectional flow paths to effect the outputted fluid and in particular a nozzle wherein at least a portion of the flow path there-through has a cross-sectional flow area smaller

than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path (see Fig. 30b). It would have been obvious to one skilled in the art at the time the invention was made to vary the cross-sectional flow area in the apparatus of Konomura and Levinson in order to have greater control over the outputted flow of fluid as taught by Okada and is well known in the art. **In regard to claims 70-75, 81-82 and 101** see the rejections stated above with respect to Konomura and Levinson.

Claims 87-88 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 6,660,011 to Levinson in further view of U.S. Patent No. 4,204,528 to Termanini.

In regards to claims 87, Konomura and Levinson discloses a medical device comprising: a proximal handle; an elongated member 2 having a proximal end, a distal end, and a lumen there between, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body; a tissue cutting end effector proximate the distal end of the elongated member, actuation of the proximal handle 14 causing the end effector to sever tissue; and a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member. Konomura and Levinson are silent with respect to wherein the flow path comprises an inlet and a plurality of outlets connecting to the inlet. Konomura teach that the number

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of openings is not limited and that a plurality of openings may be formed through which fluid may be passed (see Col. 4, Lines 36-65). Termanini teaches of an analogous surgical instrument having head 36 with apertures 40 to permit injection of a solution into the body during operation (See Figs. 1-2 and 6-7). It would have been obvious to one skilled in the art at the time the invention was made to vary the outlet area in the apparatus of Konomura and Levinson in order to have greater control over the outputted flow of fluid as taught by Termanini and is well known in the art. **In regard to claims 88 and 102** see the rejection stated above with respect to Konomura and Levinson.

(10) Response to Argument

Applicant states the combination of Konomura and Levinson fails to disclose a snare loop or a tissue cutting end effector consisting of *essentially* a snare loop. Examiner disagrees. for the purposes of searching for and applying prior art under 35 U.S.C 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising" (see MPEP 211.03). Thus, as broadly as claimed, the combination of Konomura and Levinson disclose a tissue cutting end effector that comprises a snare loop 28.

Furthermore, applicant argues that the "end effector" of Levinson requires both first and second sets of wires 20, 28. Applicant states that Levinson includes at least one additional element that materially affects the basic and novel characteristics of a snare loop. Examiner disagrees. The claim requires an end effector consisting essentially of (claims 97-100 recite "consist of") a snare loop proximate the distal end of

the elongated member, actuation of the proximal handle causing the snare loop to sever tissue. Levinson teaches of a set of wires 28 that is a snare loop and functions as the tissue cutting end effector. The device 10 includes a connector for connecting the second set of wires 28 to a source of power, for energizing the second set of wires so that the wires cut tissue captured within the second set of wires (see Fig. 5 and Col. 5, Lines 15-20). In other words, actuation of the proximal handle causes a cauterizing current to be passed through the second set of wires 28 and thus sever tissue. The first set of wires 20 are not part of the tissue cutting end effector of Levinson. The first set of wires 20 are used for capturing and retrieving the cut tissue and have no affect on the tissue cutting performed by wires 28, nor are they considered necessary for cutting tissue as a cauterizing current is not passed there-through. Moreover, it would be detrimental to the overall cutting efficiency and cauterizing effectiveness of snare loop 28, if the first set of retrieval wires 20 were to interfere with and/or materially affect the snare loop 28. Thus, as broadly as claimed, the combination of Konomura and Levinson disclose a tissue cutting end effector that consists of a snare loop.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have

been obvious to one skilled in the art to combine the device of Konomura and Levinson with Okada or Termanini in order to have various outputs of fluid flow delivery, determined by the flow path of the nozzle. Both Okada and Termanini teach of endoscopic instruments used to deliver fluid therethrough to within the body during a surgical procedure via numerous flow path configurations. Okada teaches of an analogous surgical instrument having a nozzle 374 for dispensing fluid. Okada teaches of a nozzle capable of having a large variety of configurations and cross-sectional flow paths to effect the outputted fluid and in particular a nozzle wherein at least a portion of the flow path there-through has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path (see Figs. 30a-b). It can clearly be seen in Fig 30b, that a portion of nozzle 372 has a smaller cross-sectional area of both an inlet and outlet cross-sectional areas. Termanini teaches of an analogous surgical instrument having head 36 with apertures 40 to permit injection of a solution into the body during operation (see Figs. 1-2 and 6-7). Varying the nozzle configuration in the device of Konomura and Levinson would aid in the removal of foreign matter from a target site within the body, as providing alternate nozzle configurations (such as those taught by Okada and Termanini) would allow for greater accuracy and efficiency when delivering fluids, such as contrast agents, during an assortment of different surgical procedures.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon

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hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant states that dependent claim 101 and 102 recite that "the end effector consists of" the snare loop. Examiner disagrees. Claims 101 and 102 recite wherein the end effector "consists essentially of" a snare loop. See response above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Matthew J Kasztejna/
Examiner, Art Unit 3739
6/10/8

Conferees:

/Linda C Dvorak/

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RQAS